Summary of Safety & Effectiveness
IMMUNO-TROL™ Low Cells

K013842

DEC 1 3 2001

1.0 **Submitted By:**

Lourdes Coba
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Beckman Coulter, Inc.
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2.0 **Date Submitted:**

November 19, 2001

3.0 **Device Name(s):**

3.1 **Proprietary Names**

IMMUNO-TROL™ Low Cells

3.2 **Classification Name**

Hematology quality control mixture
(21 CFR § 864.8625)

4.0 **Predicate Device:**

Candidate(s)	Predicate	Manufacturer	Docket Number
IMMUNO-TROL™ Low Cells	IMMUNO-TROL™ Cells	Beckman Coulter, Inc.	K984216

5.0 **Description:**

IMMUNO-TROL™ Low Cells is a liquid preparation of stabilized erythrocytes and leukocytes in a stabilizing solution containing BSA.

6.0 Intended Use:

IMMUNO-TROL™ Low Cells is an assayed, lysable whole blood quality control product for immunophenotyping analysis using monoclonal antibody reagents and flow cytometry. It provides a positive cell control that is processed in the same manner as a whole blood sample. This allows verification of reagent performance, and the methods used for staining of targeted cells, lysing erythrocytes, and analyzing samples by flow cytometry. The product is intended "For In Vitro Diagnostic Use."

Clinical Significance:
Immunophenotyping analysis by flow cytometry involves the identification and enumeration of targeted cells in whole blood samples. Whole blood samples are stained with monoclonal antibodies and erythrocytes are lysed prior to flow cytometric analysis. A positive control is required to verify reagent performance, sample performance, sample preparation methods, and staining procedures. A positive control should mimic a representative whole blood sample in terms of monoclonal antibody performance, erythrocyte lysing, and flow cytometric analysis.

7.0 Comparison to Predicate(s):

IMMUNO-TROL™ Low Cells is identical to the current IMMUNO-TROL™ Cells. The only difference is the reduced level of CD4.

8.0 Summary of Performance Data:

The data in the Premarket Notification on safety and effectiveness supports a finding of substantial equivalence to products already in commercial distribution. Stability studies of IMMUNO-TROL™ Low Cells support the Beckman Coulter stability claims of 90 days (open vial) and 9 months (closed vial).

This summary of safety and effectiveness is being submitted in accordance with the requirements of the Safe Medical Device Act of 1990 and the implementing regulation 21 CFR 807.92.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Lourdes Coba
Senior Regulatory Affairs Specialist
Beckman Coulter, Inc.
11800 SW 147 Avenue, M/C: 31-B06
Miami, Florida 33196-2500

DEC 1 3 2001

Re: K013842
Trade/Device Name: IMMUNO-TROL™ Low Cells
Regulation Number: 21 CFR § 864.8625
Regulation Name: Hematology Quality Control Mixture
Regulatory Class: II
Product Code: JPK
Dated: November 19, 2001
Received: November 20, 2001

Dear Mr. Coba:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K013842

Device Name: **IMMUNO-TROL™ Low Cell**

Indications for Use:

IMMUNO-TROL™ Low Cells is an assayed, lysable whole blood quality control product for immunophenotyping analysis using monoclonal antibody reagents and flow cytometry. It provides a positive cell control that is processed in the same manner as a whole blood sample. This allows verification of reagent performance, and the methods used for staining of targeted cells, lysing erythrocytes, and analyzing samples by flow cytometry. The product is intended "For In Vitro Diagnostic Use."

Immunophenotyping analysis by flow cytometry involves the identification and enumeration of targeted cells in whole blood samples. Whole blood samples are stained with monoclonal antibodies and erythrocytes are lysed prior to flow cytometric analysis. A positive cell control is required to verify reagent performance, sample performance, sample preparation, methods, and staining procedures. A positive cell control should mimic a representative whole blood sample in terms of monoclonal antibody performance, erythrocyte lysing, and flow cytometric analysis.

864.8625 Hematology quality control mixture

Identification. A hematology quality control mixture is a device used to ascertain the accuracy and precision of manual, semiautomated, and automated determinations of cell parameters such as white cell count (WBC), red cell count (RBC), platelet count (PLT), hemoglobin, hematocrit (HCT), mean corpuscular volume (MCV), mean corpuscular hemoglobin (MCH), and mean corpuscular hemoglobin concentration (MCHC).

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Josephine Bunteter

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K013842

Prescription Use ✓ OR Over-the-Counter Use _____
(per 21 CFR 801.109) Optional Format 1-2-96